

Message

From: Yan, James [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E2C11D82EEF4451BA0F6F6B0FCE82B7-YAN, JAMES]
Sent: 11/6/2020 2:48:09 PM
To: Berger, Tom C. [Berger@khlaw.com]
CC: Daniels, Rhys G. [daniels@khlaw.com]; Sullivan, Andrew [sullivan.andrew@epa.gov]
Subject: RE: P-20-00X0
Attachments: P-20-00X0_ENG Report_02_25_20_3rd_party_Redacted.pdf; P-20-00X0_HLTH Risk Assessment FINAL 04-03-20_3rd_party_Redacted.pdf

Hello. Here are the engineering and health reports for your case. These should show you how the worker inhalation risks are derived. You can use the same password as before. Please confirm receipt of the files and let us know if you have any questions. Thank you.

-James Yan

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, October 15, 2020 12:44 PM
To: Yan, James <Yan.James@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-20-00X0

James - thanks!

Tom

From: Yan, James <Yan.James@epa.gov>
Sent: Thursday, October 15, 2020 12:38 PM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Hello. Per our discussion earlier today, I think the estimated NCEL would be 0.039 mg/m³, based on the POD and normalizing between test animal exposure and expected worker exposure. Since I'm not a toxicologist and I am using a calculator I found in our files, I cannot say for certain that would be the final number, but it should be in the ballpark. If it's necessary, I might be able to get the health people to calculate the actual value.

-James Yan

From: Yan, James
Sent: Wednesday, October 14, 2020 1:18 PM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Alright. FYI, I invited another program manager to the meeting since she is an industrial hygienist and we are discussing SDS issues.

-James Yan

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Wednesday, October 14, 2020 9:38 AM
To: Yan, James <Yan.James@epa.gov>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

We (Keller and Heckman) also prefer Microsoft Teams, but let me check with the submitter.

Rhys

From: Yan, James <Yan.James@epa.gov>
Sent: Wednesday, October 14, 2020 9:18 AM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Great! What platform should we use? Microsoft Teams is the preferred platform for us.

-James Yan

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Wednesday, October 14, 2020 9:16 AM
To: Yan, James <Yan.James@epa.gov>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Yes. Let's reserve that time.

Rhys

From: Yan, James <Yan.James@epa.gov>
Sent: Wednesday, October 14, 2020 8:09 AM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

One of my meetings was canceled, so I do have time tomorrow morning. I am free from 9:30-11am. Should we schedule it for 10-11am?

-James Yan

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, October 13, 2020 5:42 PM
To: Yan, James <Yan.James@epa.gov>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Afternoon, Dr. Yan,

I have heard back from the submitter's U.S. and European colleagues. Because of the USA-EU time zone difference, mornings are strongly preferred. Specifically, would you be available this Thursday (10.16) for an hour or less any time

between 9:00 A.M, and noon EDT? If not, would you be available next Monday (10.19) or Tuesday (10.20), also any time between 9:00 A.M, and noon EDT?

Rhys

From: Daniels, Rhys G.
Sent: Tuesday, October 13, 2020 9:19 AM
To: Yan, James <Yan.James@epa.gov>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Morning Dr. Yan,

Thanks for your prompt reply. I forwarded your response to the submitter and will let you know as soon as I hear back concerning the submitter team's availability/preferences.

Rhys

From: Yan, James <Yan.James@epa.gov>
Sent: Tuesday, October 13, 2020 8:48 AM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Hello. I should be available from 2-4:30pm today and tomorrow or 3:30-4:30 on Thursday. Or does next week work better for you?

-James Yan

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Monday, October 12, 2020 3:03 PM
To: Yan, James <Yan.James@epa.gov>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Non-CBI Communication

Afternoon Dr. Yan,

The submitter asked us to arrange a video conference call with you, ourselves, and key U.S. and European company personnel to discuss current issues and path forward options for P-20-00X0. In particular, instead of conducting additional testing, we want to discuss adding a language to the SDS stating that appropriate respiratory protection should be used in case of worker exposure to dust. Please let us know when you would be available and we will be glad to arrange the call.

Rhys G. Daniels, Ph.D.
Staff Scientist
[tel:+1 202.434.4270](tel:+1202.434.4270) | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Yan, James <Yan.James@epa.gov>
Sent: Monday, October 5, 2020 2:31 PM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Great! Thank you for the update.

-James Yan

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Monday, October 5, 2020 2:26 PM
To: Yan, James <Yan.James@epa.gov>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: FW: P-20-00X0

Non-CBI Communication

Afternoon Dr. Yan,

In response to your inquiry of October 2, 2020, the submitter's European parent company today provided the following final study reports for four recently completed health and safety studies on P-20-00X0 that were conducted in connection with registrations in Asia: Algal Growth Inhibition Test (OECD 201); Acute Immobilization Test (OECD 202); Acute Dermal Irritation (OECD 404); and Acute Eye Irritation/Corrosion (OECD 405). On behalf of the submitter, we currently are processing the four study reports and plan to submit them to EPA via CDX with the next few working days.

The submitter's European parent company also indicated that it expects that five additional health and safety studies on P-20-00X0 will be finalized and available for submission to EPA via CDX within the following weeks: Activated Sludge, Respiration Inhibition Test (OECD 209); Adsorption/desorption test (OECD 106); Ready Biodegradability Test of (OECD 301B); Acute Oral Toxicity Study (OECD 423); and Skin Sensitisation Study (OECD 406).

As always, do not hesitate to let us know if you have any comments or questions concerning this matter.

Rhys

From: Yan, James <Yan.James@epa.gov>
Sent: Friday, October 2, 2020 11:13 AM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0

Hello. As I mentioned on the phone, I am taking over the case from Alie. To follow-up the phone conversation, there are a couple of questions I have:

- 1) Since we have identified environmental risk, would the company be willing to accept a consent order with a water release limit of 4 ppb? Or is the company determined to get a Not Likely determination?
- 2) Is the company trying to eliminate worker inhalation exposures or simply reduce the required respirator APF? Would they accept an APF 50?
- 3) As Alie asked in her earlier email, are any other ecotox studies forthcoming? Fish is not driving the hazard right now, so the submitted data would not reduce the hazard.

Feel free to reach out to me with any questions. Thank you!

James Jie Yan, Ph.D.

Chemist/Presidential Management Fellow

Risk Management Branch 1

New Chemicals Division

Office of Pollution Prevention and Toxics

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

Phone: 202-564-2138

Fax: 202-564-9490

Do not send CBI to this email

From: Muneer, Alie <muneer.alie@epa.gov>

Sent: Friday, October 2, 2020 10:23 AM

To: Daniels, Rhys G. <daniels@khlaw.com>

Cc: Berger, Tom C. <Berger@khlaw.com>; Yan, James <Yan.James@epa.gov>

Subject: RE: P-20-00X0

Hello Rhys, I have updated the case making the current Day 90 Oct 22, 2020. Thanks, Alie



Alie Muneer

USEPA Headquarters | OCSPP OPPT Chemical Control Division | WJC Building-East | 1200 Pennsylvania Avenue, N. W. |
Mail Code: 7405M | Washington, DC 20460 | Ph# 202 564 6369 | Fax: 202 564 9490 | Email: muneer.alie@epa.gov | Office hours:
M-F, 8am to 4:30pm

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From: Muneer, Alie

Sent: Friday, October 02, 2020 10:01 AM

To: 'Daniels, Rhys G.' <daniels@khlaw.com>

Cc: Berger, Tom C. <Berger@khlaw.com>; Yan, James <Yan.James@epa.gov>

Subject: RE: P-20-00X0

Thanks, Rhys, and I have another question on a separate topic. We have the acute fish tox test. Will there be other ecotoxicity tests (e.g., daphnid, algae) coming in or is it only the acute fish tox test? Thanks, Alie



Alie Muneer

USEPA Headquarters | OCSPP OPPT Chemical Control Division | WJC Building-East | 1200 Pennsylvania Avenue, N. W. |
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M-F, 8am to 4:30pm

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From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Friday, October 02, 2020 9:55 AM
To: Muncer, Alie <muncer.alie@epa.gov>
Cc: Berger, Tom C. <Berger@khlaw.com>; Yan, James <Yan.James@epa.gov>
Subject: RE: P-20-00X0 - Executed Email Authorization Form

Morning all,

1) After reviewing the Agency's response to the draft monitoring protocol, the company has one practical concern, for which it very shortly will be submitting a follow-up non-CBI email seeking additional clarification.

(2) In the meantime, we authorize another 15-day suspension of review for P20-00X0.

As always, do not hesitate to contact us if you have any comments or questions concerning this matter.

Rhys G. Daniels, Ph.D.
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1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Muncer, Alie <muncer.alie@epa.gov>
Sent: Friday, October 2, 2020 9:44 AM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Berger, Tom C. <Berger@khlaw.com>; Yan, James <Yan.James@epa.gov>
Subject: RE: P-20-00X0 - Executed Email Authorization Form

Hello Rhys: Has the company decided to move forward to conduct sampling? What is the status?

Also, the current Day 90 is Oct 7. Do you approve of another 15-day suspension?

Thanks, Alie



Alie Muncer

USEPA Headquarters | OCSPP OPPT Chemical Control Division | WJC Building-East | 1200 Pennsylvania Avenue, N. W. |
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From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Friday, September 18, 2020 11:54 AM
To: Yan, James <Yan.James@epa.gov>
Cc: Muneer, Alie <muneer.alie@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Subject: RE: P-20-00X0 - Executed Email Authorization Form

Thank you, Dr. Yan.

We received, successfully opened, and currently are reviewing the two password-protected documents you forwarded for P-20-00X0. We will review these with the submitter and then get back to the Agency,

Rhys G. Daniels, Ph.D.
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From: Yan, James <Yan.James@epa.gov>
Sent: Friday, September 18, 2020 11:09 AM
To: Daniels, Rhys G. <daniels@khlaw.com>
Cc: Muneer, Alie <muneer.alie@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>
Subject: [Not Virus Scanned] RE: P-20-00X0 - Executed Email Authorization Form

Hello. Here are password-protected documents for your case. I will follow up separately with the password. Please confirm receipt of the files and let us know if you have any questions regarding accessing them. Thank you.

James Jie Yan, Ph.D.
Chemist/Presidential Management Fellow
New Chemicals Management Branch
Chemical Control Division
Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Phone: 202-564-2138
Fax: 202-564-9490
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From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Wednesday, May 27, 2020 1:33 PM

To: Muneer, Alie <muneer.alie@epa.gov>

Subject: P-20-00X0 - Executed Email Authorization Form

Dear Ms. Muneer,

As promised, attached is the executed email authorization form for P-20-00X0.

As before, do not hesitate to contact us if you have any comments or questions concerning this matter.

Rhys G. Daniels, Ph.D.

Staff Scientist

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1001 G Street NW, Suite 500 West | Washington, DC 20001

